



DCHQ - 0493 - 12424

American Cyanamid Company  
One Cyanamid Plaza  
Wayne, NJ 07470



8EHQ-93-12424  
INIT 09/14/93

H. Michael D. Utidjian, M.D.  
Corporate Medical Director

September 8, 1993

Document Processing Center (TS-790)  
Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 M Street S.W.  
Washington, DC 20460



88930000441

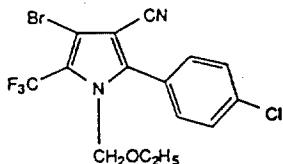
Attention: Section 8(e) Coordinator

Dear Sir/Madam:

(A)

The purpose of this letter is to inform you, under TSCA Section 8(e), of results of an dermal sensitization study using the Buehler Closed Patch Method communicated to us on August 25, 1993. The study was conducted with AC 303,630 10% EC formulation. The active ingredient a research material, designated, generically as, a substituted pyrrole, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile (CA).

## Compound Structure



## Dermal Sensitization Study in Guinea Pigs (T-400-9303-018)

The test material when tested for dermal sensitization using the Buehler Closed Patch Method produced a mild sensitizing reaction which was confirmed upon rechallenge. However when the technical material was tested the test material was not considered to be a sensitizer. Available information on the excipients used support our belief that the sensitization was a response due to the excipients used in the formulation (New Kalgen 530 and New Kalgen D-625).

We are currently evaluating the significance of these results. This material is under research and development as an insecticide.

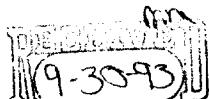
If further information is required, please contact K.A. Traul, Ph.D. at 609-799-0400 ext. 2701.

Sincerely,

H. Michael D. Utidjian, M.D.  
Corporate Medical Director

REC'D  
11/11/93  
11:50

CONTAINS NO CB





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PESTICIDES AND TOXIC  
SUBSTANCES

H. Michael D. Utidjian, M.D.  
Corporate Medical Director  
American Cyanamid Company  
One Cyanamid Plaza  
Wayne, New Jersey 07470

APR 12 1994

This letter formally acknowledges EPA's receipt of information submitted by your organization under Section 8(e), the "substantial risk" information reporting provision of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA Section 8(e) Document Control Number (i.e., 8EHQ-0000-0000 Init.) assigned by EPA to your submission(s). Please refer to this cited number when submitting follow-up or supplemental information.

Please note that all submitted correspondence will be placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA Section 8(e) policy statement (43 FR 11110, March 16, 1978).

Confidential submissions submitted pursuant to the TSCA Section 8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims, because substantiation of CBI claims is required at the same time the 8(e) CAP is submitted to EPA. (If not done so already, please ensure that this information is provided to the Agency). When substantiating any/all claims, answer the questions detailed in the following attachment.

For NON-CAP submissions, any confidentiality claims should be supported by submission of information as described in the attachment(s).

12424 A

CATS DATA  
Version 8 09/10/0993 - 17424 SEO A

PEI(M) SUPP FLWP

TRANSMITTER NAME: American Cyanamid  
Company

INFORMATION REQUESTED: FLWP DATE

- 0501 NO INFO REQUESTED
- 0502 INFO REQUESTED (TECH)
- 0503 INFO REQUESTED (VOL ACTIONS)
- 0504 INFO REQUESTED (REPORTING RATIONALE)
- 0505 REFER TO CHEMICAL SCREENING
- 0506 CAP NOTICE

IR DATE: 09/08/93 OTC DATE: 09/14/03 CARO DATE: 09/30/93

CHEMICAL NAME:

~~Pyrethrin~~ → ~~Confidential~~  
 $\text{1H-pyrcrole-3-carbonitrile, 4-bromo-}$   
 $\text{-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-}$

FORMATION TYPE:

FORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:
ONCO (HUMAN)	0216	EPICLIN	0241	HUMANO (ANIMAL)
ONCO (ANIMAL)	0217	HUMAN EXPOS (PROD CONTAM)	0242	HUMANO (HUMAN)
CELL TRANS (IN VITRO)	0218	HUMAN EXPOS (ACCIDENTAL)	0243	CHEMPHY3 PROP
MUTA (IN VITRO)	0219	JUAN EXPOS (MONITORING)	0244	CLASTO (IN VITRO)
MUTA (IN VIVO)	0220	ZO/AQUA TOX	0245	CLASTO (ANIMAL)
REPROTERATO (HUMAN)	0221	CNV. OCCURRENCE	0246	CLASTO (HUMAN)
REPROTERATO (ANIMAL)	0222	EMER. INC. OF ENV CONTAM	0247	DNA DAMAGE/REPAIR
NEURO (HUMAN)	0223	RESPONSE REQUEST DELAY	0248	PRODUCE/PROC
NEURO (ANIMAL)	0224	PROD/COMP/CHM ID	0249	MEADS
ACUTE TOX (HUMAN)	0225	REPORT/NO RATIONALE	0250	OTHER
CHR. TOX (HUMAN)	0226	CONFIDENTIAL		
ACUTE TOX (ANIMAL)	0227	ALLERG (HUMAN)		
SUB ACUTE TOX (ANIMAL)	0228	ALLERG (ANIMAL)		
SUB CHRONIC TOX (ANIMAL)	0229	METAB/PHARMACO (ANIMAL)		
CHRONIC TOX (ANIMAL)	0230	METAB/PHARMACO (HUMAN)		

BASIS DATA:

NON-CHLORINATED

Yes (CONTINUE)

NO (CONTINUE)

REFER.

DETERMINING

Non-Cap

TOXICOLOGICAL CONCERN:

G P

LOW

MED

HIGH

VOLUNTARY ACTIONS:

R:D Insecticide

- 0501 NO ACTION REPORTED
- 0502 STUDIES PLANNED/UNDERWAY
- 0503 NOTIFICATION OF WORK (MANUFACTURER)
- 0504 LABEL/ASSETS CHANGES
- 0505 PROCESS/HANDLING CHANGES
- 0506 APP USE DISCONTINUED
- 0507 PRODUCTION DISCONTINUED
- 0508 CONFIDENTIAL

CATS DATA: 0993 - 12474 seq. A

PE INFO SUPP FLWP

TRANSMITTER NAME: American Cyanamid  
Company

INFORMATION REQUESTED: FLWP DATE

- 6501 NO ACTION REPORTED
- 6502 STUDIES PLANNED/IN PROGRESS
- 6503 NOTIFICATION OF WORK PLAN/NOTIFICATION
- 6504 LABEL/MSDS CHANGES
- 6505 PROCESS/HANDLING CHANGES
- 6506 API/USE DISCONTINUED
- 6507 PRODUCTION DISCONTINUED
- 6508 CONFIDENTIAL

DISPOSITION:

- 653 REFER TO CHEMICAL SCREENING
- 654 CAP NOTICE

IN DATE: 09/08/93 ONS DATE: 09/14/93 CRRAD DATE: 09/30/93

RECEIVED BY: John F. Hart

CASE: 122453-73-0

1H-pyccole-3-carbonitrile, 4-bromo-  
-(4-chlorophenyl)-1-(ethoxy methyl)-5-(trifluoromethyl)-

FORMATION DATE:

L.F.C.	FORMATION DATE:	L.F.C.	FORMATION DATE:
01	ONCO (HUMAN)	0216	EPICLIN
02	ONCO (ANIMAL)	0217	HUMAN EXPOS (PROD CONTAM)
03	CELL TRANS (IN VITRO)	0218	HUMAN EXPOS (ACCIDENTAL)
04	MUTA (IN VITRO)	0219	HUMAN EXPOS (MONITORING)
05	MUTA (IN VIVO)	0220	DV/QA TOX
06	REPROTELEATO (HUMAN)	0221	CHV OCCUR/BELATE
07	REPROTELEATO (ANIMAL)	0222	EMER. SOC OF ENV CONTAM
08	NEURO (HUMAN)	0223	RESPONSE REQUEST DELAY
09	NEURO (ANIMAL)	0224	PRODCOMP/CHM ID
10	ACUTE TOX (HUMAN)	0225	REPORTING RATIONALE
11	CHR. TOX (HUMAN)	0226	CONFIDENTIAL
12	ACUTE TOX (ANIMAL)	0227	ALLERO (HUMAN)
13	SUB ACUTE TOX (ANIMAL)	0228	ALLERO (ANIMAL)
14	SUB CHRONIC TOX (ANIMAL)	0229	METABPHARMACO (HUMAN)
15	CHRONIC TOX (ANIMAL)	0230	METABPHARMACO (ANIMAL)

BLACKLIST: NON-CH INVENTORY

- YES (CONTINUE) YES (DROP/REFUSE)
- NO (CONTINUE) NO (DROP)
- DETERMINING REFER.

SPECIES:

G9

TOXICOLOGICAL CONCERN:

LOW Dermal sensitization

RID Insecticide

MED

HIGH

DISPOSITION:

NON-CAP

COMMENTS: Non-Cap

8(e)-12424A

LOW--Dermal sensitization

Using the Buehler closed patch method, the formulation produced a mild sensitizing reaction in guinea pigs at challenge and rechallenge. However, when the technical material was tested, the material was not considered to be a sensitizer.